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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/509,847 | 10/01/2004 | Robert Andrew Slade | 469.1113 | 4322 |
| 21171 7590 11/18/2008 STAAS & HALSEY LLP SUITE 700 1201 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | | | |
| EXAMINER | | | | |
| LEACH, CRYSTAL I | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3737 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 11/18/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,847

Applicant(s)

SLADE ET AL.

Examiner

CRYSTAL I. LEACH

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

Response to Arguments

1. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

DETAILED ACTION

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arenson et al. (6,304,769) in view of Kucharczyk et al. (6,298,259) or Hanley et al. (US 2003/0191385).

Arenson et al. teach an imaging and steering catheter assembly comprising a magnetic field generating assembly (see Abstract) operable in a first mode to generate a first magnetic field in a working volume located, the first magnetic field being suitable for use in a catheter steering procedure, and in a second mode to generate a second, static magnetic field in the working volume suitable for conducting a magnetic resonance imaging process (MRI), the second magnetic field being more uniform in the working volume than the first magnetic field (see col. 10, lines 40-44 and col. 13, lines 58-60); and a catheter capable of being steered in a direction determined by an interaction with the first magnetic field (see col. 3, lines 29-37; col. 11, lines 26-43; and col. 10, line 66 - col. 11, line 6). Arenson et al. teach generating a magnetic field using,

for example, a superconductor magnet (col. 7, lines 58-60), which therefore implies that the system as taught by Arenson et al. is capable of generating a static magnetic field. Examiner notes that it is obvious that MRI systems are capable of generating steady, homogeneous magnetic fields. Furthermore, it would be obvious to one of ordinary skill in the art that a MRI system creates a magnetic field external to the system. For this reason, shield rooms and/or areas are warranted when operating an MRI assembly. Arenson et al. teach the magnetic field generating assembly (see col. 7, lines 55-58 and col. 5, lines 39-48), for example, an MRI apparatus (see col. 7, lines 60-62), comprising electromagnets (see col. 5, lines 39-48; col. 4, lines 58-62) whose currents are capable of being adjusted or reversed (see col. 11, lines 4-14) within a working range including zero (see col. 11, lines 21-23 and col. 4, lines 29-42) and are capable of being adjusted to a fixed setting (see col. 13, lines 51-56). Arenson et al. teach magnets capable of generating pulsed magnetic fields with linear gradients (see col. 8, lines 19-25) in mutually orthogonal X and Y directions respectively, orthogonal to the Z direction, during the MR process and substantially static fields in the X and Y directions respectively during the steering procedure (see col. 11, lines 31-44 and col. 5, lines 13-15). Arenson et al. teach one or more magnets being superconducting electromagnets (see col. 7, lines 58-60). Regarding claims 7 and 8, Arenson et al. teach a magnetic dipole of a catheter tip capable of being switched on in steering mode and off in imaging mode (see col.10, line 66 – col. 11, line 23 and col. 10, lines 40-44). Arenson et al. teach a method of providing an imaging and steering catheter assembly comprising a magnetic field generating assembly (see Abstract) operable in a first mode to generate

a first magnetic field in a working volume located the assembly, the first magnetic field being suitable for use in a catheter steering procedure, and in a second mode to generate a second, static magnetic field in the working volume suitable for conducting a magnetic resonance imaging process (MRI), the second magnetic field being more uniform in the working volume than the first magnetic field (see col. 10, lines 40-44 and col. 13, lines 58-60); and a catheter capable of being steered in a direction determined by an interaction with the first magnetic field (see col. 3, lines 29-37; col. 11, lines 26-43; and col. 10, line 66 - col. 11, line 6); inserting the catheter into a body (col. 12, line 43); steering the catheter through the body (col. 12, lines 43-44) by selectively operating the assembly in the first mode (col. 12, lines 45-52; col. 10, line 66 – col. 11, line 6; and col. 13, lines 58-60); and obtaining an image of part of the body by operating the assembly in the second imaging mode (col. 13, lines 9-11). See col. 13, line 66 – col. 14, lines 1. Furthermore, it would be obvious to one of ordinary skill in the art that a MRI system creates a magnetic field external to the system. For this reason, shield rooms and/or areas are warranted when operating an MRI assembly. Arenson et al. do not explicitly teach that the working volume is located outside the magnetic field generating assembly.

Kucharczyk et al. teach the limitations of the claimed imaging and catheter steering assembly of the present invention wherein the working volume is located outside the assembly (see col. 3, l. 45-60; col. 11, l. 16-39; col. 12, l. 60 - col. 13, l. 11 and fig. 1-2). Hanley et al. also teach the limitations of the claimed imaging and

catheter steering assembly of the present invention wherein the working volume is located outside the assembly (see p. 1, l. 25 – p.2, l. 35 and p. 6, l. 6 – p. 7, l. 16).

It would have been obvious to one of ordinary skill in the art to modify the system of Arenson et al. to work both in and outside of the working volume of the assembly in order to enhance the utility of the device.

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arenson et al. (6,304,769) in view of Kucharczyk et al. (6,298,259) or Hanley et al. (US 2003/0191385) and further in view of Breneman et al. (5,412,363).

Arenson et al. in view of Kucharczyk et al. or Hanley et al. do not specifically teach that the coils are made from high temperature superconductor.

Breneman et al. teach the use of a superconducting coil formed of high temperature superconductor (col. 5, lines 38-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include coils formed of high temperature superconductor in the combined invention, in light of the teachings of Breneman et al. in order to increase safety limits when generating an optimal amount of current within the desirable magnetic field strengths.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arenson et al. (6,304,769) in view of Kucharczyk et al. (6,298,259) or Hanley et al. (US 2003/0191385) and further in view of McDougall et al. (5,680,044).

Arenson et al. in view of Kucharczyk et al. or Hanley et al. do not explicitly teach the magnets comprising electrical coils capable of exhibiting substantially zero mutual inductance.

McDougall et al. teach magnets of a magnetic field generating assembly comprising electrical coils (col. 2, lines 3-5) capable of exhibiting substantially zero mutual inductance (col. 10, lines 51-54).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include magnets comprising electrical coils capable of exhibiting substantially zero mutual inductance in the combined invention, in light of the teaching of McDougall et al. in order to enhance the signal-to-noise ratio and to avoid undesirable effects resulting from residual flux leakage.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal I. Leach whose telephone number is 571-272-5211. The examiner can normally be reached on Monday through Friday, 8 am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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